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May 31, 2024

By ECF

Hon. Douglas E. Arpert, U.S.M.J. (Ret.)
Three Gateway Center
100 Mulberry Street
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Newark, New Jersey 07102

**Re: United States ex rel. Silbersher v. Janssen Biotech Inc., et al.,
Civil Action No. 19-12107 (MEF-CLW)**

Dear Judge Arpert:

Defendants Johnson & Johnson (“J&J”), Janssen Biotech, Inc., Janssen Oncology, Inc., and Janssen Research & Development, LLC (collectively, “Defendants”) submit this letter in the above-captioned matter pursuant to Civil Local Rule 37.1 governing discovery disputes, the Court’s Order referring discovery disputes to the Special Master (ECF No. 331), and the Special Master’s Order regarding unresolved discovery issues (ECF No. 337).

This letter asks the Court to direct Relator to provide complete responses to the Interrogatories described below.

I. Background

The Parties previously submitted a joint dispute letter to Judge Kiel regarding Relator’s deficient responses to Defendants’ Interrogatories on November 14, 2023 (the “November 14

Letter”). ECF 294. Judge Kiel advised the Parties that he deemed the Interrogatories to be contention interrogatories that should not be served until 60 days prior to the close of fact discovery, pursuant to Local Rule 33.1(d). *See* ECF 311 at 51–52. Accordingly, Judge Kiel deferred a resolution of the merits of this dispute until that time.

In accordance with Local Rule 33.1(d), Defendants re-served Relator with the disputed Interrogatories on April 25, 2024. Relator has not amended or supplemented his responses. The parties therefore are at an impasse.¹

II. Relator Must Provide Complete Responses to Defendants’ Interrogatories.

Defendants respectfully request that this Court direct Relator to submit complete responses to the following Interrogatories, each of which ask Relator to provide information regarding his allegations that Defendants submitted false claims to federal and state governments. Identifying with specificity the specific claims, or category of claims, Relator alleges to be false is foundational to filing suit under the False Claims Act (“FCA”). Further, obtaining complete responses to these Interrogatories is vital to enable Defendants to properly prepare their defense and to appropriately question Relator in his deposition. Relator bears the burden of proof in this FCA case. Until Defendants understand the specific claims that Relator intends to advance at trial, and the evidence he plans to rely upon to support each element of those claims, Defendants cannot meaningfully evaluate what defenses they will or will not advance at trial. These Interrogatories are designed to elicit precisely this information.

This is particularly crucial in light of Relator’s shifting theories of liability in this case. With just days left in fact discovery, Relator is now advancing a theory of fraud that finds scant

¹ The Parties met and conferred on these issues before submitting the November 14 Letter, including on October 12, 19, and 23, 2023. After Defendants re-served the Interrogatories, the Parties met and conferred on May 28, 2024 and were unable to reach a resolution.

purchase in his Complaint, and in no event with the level of particularity required by Rule 9(b). ECF 354 at 11–13 (Defendants’ Opposition to Relator’s Motion for *In Camera* Review Pursuant to the Crime-Fraud Exception). At this late juncture, it is beyond time for Relator to fully answer these Interrogatories, explain what he contends, and what facts he purports to rely upon to support those claims.

A. Interrogatories 4, 5, 6, & 7

The November 14 Letter specifically addresses Relator’s deficient Responses to Defendants’ Interrogatory Nos. 4, 5, 6, and 7. Defendants ask the Court to direct Relator to provide complete responses to these Interrogatories for the reasons stated in that Letter, attached for the Court’s convenience as Exhibit 1.

B. Interrogatories 10, 11, 17, & 18

Defendants also ask the Court to direct Relator to provide complete responses to Defendants’ Interrogatory Nos. 10, 11, 17, and 18. As stated in the November 14 Letter, to the best of Defendants’ understanding, Relator had represented to Defendants at that time that he would amend his responses to Interrogatories 10 and 11, which closely relate to Interrogatories 17 and 18. ECF 294 at 6. Defendants thus did not seek relief as to these four interrogatories in that Letter. *Id.* at 6 n.2. Since then, however, Relator has not amended these responses and has indicated that he does not plan to do so. Defendants therefore ask the Court to direct Relator to provide complete responses.

Each of these interrogatories asks Relator to provide information regarding his allegations that Defendants submitted false claims to federal and state governments. More specifically, these Interrogatories ask Relator to describe the following categories of information:

- the false or misleading nature of each alleged false claim or category of claims (Defendants’ Interrogatory 10);

- each express and/or implied false certification he contends that Defendants submitted (Defendants' Interrogatory 11); and
- the processes through which he alleges those claims were submitted to either the federal or state governments (Defendants' Interrogatory 17, 18).

This information plainly comes within the proper scope of a contention interrogatory. *See, e.g., Santos v. Carrington Mort. Servs.*, 2016 WL 7018523 (D.N.J. Nov. 30, 2016) (“Contention interrogatories are permissible to ask a party to state what it contends; to state whether it makes a specified contention; to state all the facts upon which it bases a contention; to take a position, and explain or defend that position, with respect to how the law applies to facts; or to state the legal or theoretical basis for a contention.”); *Conopco, Inc. v. Warner-Lambert Co.*, 2000 WL 342872, *4 (D.N.J. Jan. 26, 2000).

Interrogatories 10 and 11: Relator fails to identify the false or misleading nature of the alleged false claims.

These Interrogatories ask Relator to describe with particularity the “false or misleading nature of each claim” for which he contends Defendants are liable (No. 10); and “each and every false certification, express or implied” that he contends Defendants “submitted to a Federal and/or State Government” (No. 11).

Relator’s responses are vague and entirely insufficient. He states only at the greatest level of generality that Defendants “falsely implied that Zytiga’s prices were fair and reasonable,” such that each and every claim they submitted to the federal or state governments was false. Ex. 1-A, Relator’s Responses to Defendants Interrogatories (Dec. 5, 2022). But Relator fails to describe those claims or certifications with any specificity, as the Interrogatories require.

This is a crucial omission. To prevail on an implied false certification theory under the FCA, Relator must prove that Defendants “submit[ted] a claim for payment that makes *specific* representations about the goods or services provided, but knowingly fails to disclose the

defendant's noncompliance with a statutory, regulatory or contractual requirement." See *Universal Health Servs. Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 1996 (2016). Thus, at the very minimum, for each claim—or category of claims—that Relator alleges is false, he must identify:

- the specific claim(s) at issue—i.e., the specific “request or demand for . . . money or property” made by Defendants—and the process through which Defendants submitted such claim(s), 31 U.S.C. § 3729(b)(2);
- the specific representation(s) that Defendants allegedly made that render the claim(s) false; and
- the specific statutory, regulatory, or contractual requirement(s) with which Defendants allegedly failed to comply.

Relator's responses to these Interrogatories provides none of this simple and essential information.

Further, to appropriately respond to these Interrogatories—which merely mirror the statutory elements Relator must prove at trial—Relator must provide these three categories of information for *each* federal or state payor that Relator asserts was defrauded. Relator has placed at issue a myriad of federal and state healthcare programs. Each of them has its own regulations and conditions for payment. Relator alleges that Defendants falsely and knowingly certified compliance with these conditions, *see, e.g.*, ECF 63, Second Amended Complaint (“SAC”) ¶¶ 110, but he refuses to disclose what *specific* “conditions for participation” he claims were relevant or material to the various government payors’ decisions to pay these claims, or what *specific* representations Defendants made regarding their compliance with these conditions that he alleges were false.

Until Relator provides answers to these straightforward questions, Defendants cannot understand the specific allegations Relator intends to advise at trial and the evidence he plans to rely upon to support each of those claims, Defendants cannot adequately or appropriately prepare

their defenses. The Interrogatories Defendants have posed to Relator are designed to elicit precisely this information.

Interrogatories 17 & 18: Relator fails to disclose the processes by which he contends that Defendants' allegedly false claims were submitted to federal or state governments.

Relator's responses to Interrogatories 17 and 18 are similarly inadequate. These Interrogatories seek information on the processes and mechanisms through which Relator alleges that false claims were submitted and processed by the government healthcare programs he claims were defrauded in this case. Therefore, they plainly relate to the evidence that will be necessary for Relator to establish the causation and materiality elements he is required to prove under the FCA.

Again, as noted above, Relator has placed at issue a myriad of federal and state healthcare programs, each with its own regulations, conditions for payment, and procedures for receiving, reviewing, processing and ultimately paying claims. Relator thus must explain the claim submission process with particularity for *each* federal or state healthcare program he claims was defrauded.

Yet Relator's responses do none of that work. He states at the highest level of generality that "each Government program has their own set of requirements," and claims that they "do not affect Defendants' liability." Ex. 1-B, Relator's Answers to Defendants' Second Interrogatories at 6 (Mar. 23, 2023). That is simply incorrect as a matter of law.

To prove causation under the FCA, Relator must demonstrate that Defendants actually submitted or caused the submission of false claims for payment. See 31 U.S.C. § 3729(a)(1). "[E]vidence of how the claim makes its way to the government"—i.e., the process or mechanism through which claims are submitted to the government—is directly relevant to this inquiry. *United States ex rel. Petratos v. Genetech Inc.*, 855 F.3d 481, 492 (3d Cir. 2017). Similarly, Relator must prove that the Defendants' allegedly false statements were "material" to the government's decision to

make a payment on the particular claims at issue. *Id.* at 489; *Universal Health Servs., Inc. v. U.S. ex rel. Escobar*, 579 U.S. 176, 192–93 (2016). The process through which each government agency at issue receives, reviews, processes, and ultimately pays a particular claim invariably is critical to the causation and materiality analyses. Defendants are thus entitled to discovery on from Relator on how he intends to establish these necessary elements of his claim.

* * *

Finally, Defendants note that Relator argued in the Parties' most recent meet-and-confer that Defendants have not timely raised his deficient responses to the foregoing Interrogatories for two reasons. Relator is mistaken.

First, Relator argued that Judge Kiel required all written discovery—including contention interrogatories—to be served by February 15, 2024. But Judge Kiel explicitly exempted contention interrogatories from that deadline. ECF 326 at 29–30 (“THE COURT: [After] February 15th . . . if anybody wants to issue any further written discovery, they would have to make an application to the Court. . . . As I said, . . . *I'm also going to give the parties an opportunity to have contention - - . . . - interrogatories later.* But really written discovery as to fact issues should be concluding [on] February 15.”) (emphasis added)).

Second, Relator argued that Defendants should have raised this issue in one of the prior briefing windows established by the Special Master’s April 12, 2024 Order, ECF 337. But this issue was not ripe at those times. As noted, Judge Kiel advised the Parties that he deemed these Interrogatories to be contention interrogatories that should not be served until 60 days prior to the close of fact discovery, pursuant to Local Rule 33.1(d). *Supra* at 2, ECF 311 at 51–52. Defendants abided by that instruction, re-served the Interrogatories on April 25, 2024 in compliance with the Local Rule, and provided Relator with 30 days to respond. The issue therefore is now ripe for the Court’s decision.

Respectfully yours,

SILLS CUMMIS & GROSS P.C.

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